

**America's Health
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September 25, 2009

California Privacy and Security Advisory Board
c/o: Ms. Bobbie Holm, Chief, Policy Branch
California Health and Human Services Agency
California Office of Health Information Integrity
1600 9th Street, Room 460
Sacramento, CA 95814

***Re: CalPSAB Health Information Exchange Patient HIE-Consent Guidelines
(Dissenting Opinion)***

Dear Board Members:

I am writing today on behalf of America's Health Insurance Plans (AHIP) to voice concerns and note our dissent regarding the patient consent recommendations that was approved by the California Privacy and Security Advisory Board (CalPSAB). AHIP is the national association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of health insurance products in the commercial marketplace and also have demonstrated a strong commitment to participation in public programs.

AHIP continues to be an active participant on the CalPSAB and our members appreciate the opportunity to be engaged in the dialogue regarding the development of privacy and security guidelines for the exchange of health information in California. Our members consider privacy and security to be key components of any program that involves the receipt, exchange, or storage of individually identifiable health information. AHIP recognizes the important work that has been done by the CalPSAB and supports efforts that further the exchange of health information in a secure manner. We believe that the health information exchange (HIE) has the potential to increase the quality of care and help contain health care costs for Californians.

A crucial part of the recent CalPSAB discussions has been focused on the patient consent guidelines for participation in the HIE and a disagreement among stakeholders has emerged. The basis of the disagreement is whether consumers should be required to affirmatively agree to "opt-in," or should instead have the ability to "opt-out," -- with appropriate notice provided to consumers of their rights and options. On September 16, 2009, the CalPSAB voted to pursue a hybrid approach to patient consent that incorporates an "opt-out" approach for direct treatment, and an "opt-in" process for other uses and sensitive information. AHIP, the California Association of Physician Groups, and the World Privacy Forum all voted against this proposal.



Specifically, AHIP and our members are concerned that the proposed hybrid approach is inconsistent with federal privacy and security standards, will be confusing to consumers, and will inhibit compliance with other statutory and regulatory requirements. What follow are details of our concerns.

1. The Hybrid Approach to Patient Consent is Inconsistent with Federal Standards

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security standards establish uniform procedures for the use and disclosure of protected health information (PHI). The federal requirements provide uniform definitions and create a consistent and reliable framework that protects PHI. Additionally, there has been a movement toward uniformity in the use and exchange of health information, with the goal of a nationwide interoperable system for the secure exchange of PHI. Development of conflicting standards at the state level would only stall the move toward a secure nationwide information exchange. We urge the adoption of an approach for the California HIE that is consistent with HIPAA, and respectfully submit that the hybrid model recommended by CalPSAB conflicts with these federal requirements.

- *Opt-In vs. Opt-Out.* We note that the HIPAA privacy and security regulatory standards do not require an individual's consent or an "opt-in" process for uses or disclosures of PHI. Instead, the federal privacy and security rules mandate that covered entities provide notice to consumers regarding how their PHI may be used and disclosed and allows consumers to request restrictions on the uses and disclosures of his or her PHI. This uniform approach sets a clear and consistent expectation regarding how PHI should be protected, when health information can be legitimately used and disclosed, and also includes individual rights for consumers. The federal regulatory requirements should be used as a foundation for nationwide HIEs. The hybrid model proposed by CalPSAB appears to directly conflict with the federal standards by requiring consumers to "opt-in" for uses other than direct treatment.
- *Treatment, Payment, and Health Care Operations.* HIPAA also recognizes that payment and health care operations are equally important functions within the health care system as treatment when it comes to the use and disclosure of PHI. All of these functions are dependent on the efficient flow of information and should not be treated differently or require separate consents. For example, information regarding a patient's health status is critical to effective health care operations, such as care and disease management programs which have been shown to lower costs while improving the overall health of the consumer. The proposed hybrid consent model would create an additional and unnecessary step that would not only inhibit the continuation of these important programs, but would also inhibit their effectiveness and threaten future innovations. We submit that disclosures and uses that are currently allowed equally under HIPAA (e.g.,



treatment, payment, and health care operations) should also be treated equitably under the California HIE. In addition, we respectfully request that the CalPSAB be directed to adopt the HIPAA definitions for treatment, payment, and health care operations. This will ensure that the national and individual state frameworks do not include inconsistent standards or create unnecessary barriers to the exchange of health information.

2. The Hybrid Approach to Patient Consent Will be Confusing to Consumers

AHIP members are also concerned that the hybrid model recommended by CalPSAB will create a system that is confusing for consumers by establishing different consent standards for the use and disclosure of the same information among interested parties in the health care system. The confusion is further exacerbated by the establishment of different consent standards based on the format of health information (e.g., electronic or paper). It is unclear why a single consent to the use and disclosure of information – regardless of its form – would not be sufficient from a privacy and security perspective.

In addition to being unnecessarily burdensome for providers and health insurance plans, the hybrid consent model would create duplicative consent requirements that consumers will likely find frustrating and confusing. As information is needed by various parties throughout the health system, consumers could receive multiple consent forms that may be required after the patient encounter has commenced. Moreover, the costs of acquiring consent for the exchange of HIE for each and every patient for each and every claim or information will be costly and will impede the exchange of necessary data throughout California.

3. The Hybrid Approach to Patient Consent Will Inhibit Compliance with Other Laws

Finally, we note that the recommended hybrid approach to patient consent will inhibit compliance with other legal requirements. Health care providers need information to effectively treat patients, and health insurance plans need access to the same information to submit timely payment and comply with other laws and regulations. Specifically, California law imposes a series of affirmative duties on health plans that mandate the use and disclosure of PHI. Examples of pertinent statutory duties imposed under the Knox-Keene Act include:

- Continuity of Care. Health plans must assure continuity of care and ready referrals of patients to other providers consistent with good professional practice. Compliance with this requirement necessarily requires access to medical records, which include PHI. *See Cal. Health & Safety Code §1367(d) and Cal. Code Regs. Tit. 28, § 1300.67.1.*
- Quality Assurance. Health plans must continually review the quality of care provided enrollees, the performance of medical personnel, and the utilization of services, facilities and costs. Compliance with this requirement necessarily requires access to medical

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records, which include PHI. *See Cal. Health & Safety Code §1370.*

- *Emergency services.* Health care service plans are responsible for any emergency services their enrollees require, including services provided outside the health plan's network. Compliance with this requirement necessarily requires the use and disclosure of PHI as the plan will need to share information (such as medical history) with the emergency facility or provider who, in turn, will need to disclose to the plan information on the specific medical services provided. *See Cal. Health & Safety Code §1371.4.*

The establishment of standards for the use and disclosure of PHI in California must avoid erecting unnecessary and costly barriers that impede the flow of information and frustrate compliance with existing statutory and regulatory requirements, such as those detailed above.

For the reasons outlined above, we urge a rejection of the CalPSAB recommendation for patient consent that establishes a hybrid model. It is imperative that the California HIE adopt an "opt-out" consent process that aligns with the national, uniform framework established under HIPAA and includes identical procedures for treatment, payment, and health care operations activities. We further recommend that the consent guidelines specifically acknowledge HIPAA's allowance for the use and disclosure of PHI without separate consent for these functions, and that the state rules do not change or affect the HIPAA approved disclosures. Alternatively, we urge a requirement to further negotiations among interested parties to develop a uniform patient consent framework that can be consistently applied across all functions of the health care system. This will avoid the confusion and costly administrative procedures associated with the current hybrid framework recommendation which we believe is unworkable for the reasons noted above.

We appreciate the opportunity to provide you with our comments and thank you for taking our views into consideration. If you have questions, please do not hesitate to contact me at 562-429-7493 or lgassaway@ahip.org.

Sincerely,

A handwritten signature in black ink that reads "Leanne Gassaway".

Leanne Gassaway
Regional Director, State Advocacy